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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/063,978	04/21/1998	ROBERT J. OBREMSKI	45D-1750(641	5283

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EXAMINER

HINES, JANA A

ART UNIT PAPER NUMBER

1645

DATE MAILED: 01/22/2003

34

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/063,978

Applicant(s)

OBREMSKI ET AL

Examiner

Ja-Na Hines

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 November 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-36 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-36 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Amendment Entry

1. The amendment filed November 6, 2002 has been entered. Claims 1, 23 and 26 have been amended. Claims 29-36 have been newly added. Claims 1-36 are under consideration in the office action.

Withdrawal of Rejections

2. The following rejections have been withdrawn in view of applicants' amendments:

a) The rejection of claims 1-4, 13-19, 21 and 23-28 under 35 U.S.C. 103(a) as being unpatentable over Ekins et al., (EP 304,202) in view of Ekins et al., (J. of Clinical Immuno.);

b) The rejection of claims 1-4, 13-19, 21 and 23-28 under 35 U.S.C. 103(a) as being unpatentable over Ekins et al., (EP 304,202) in view of Ekins et al., (Analytica Chimica Acta.);

c) The rejection of claims 5-10 under 35 U.S.C. 103(a) as being unpatentable over Ekins et al., (EP 304,202) and either Ekins et al., (J. of Clinical Immuno.) or Ekins et al., (Analytica Chimica Acta.), in further view of Ullman et al., (US Patent 5,512,659) is maintained. Ekins et al., (EP 304,202), Ekins et al., (J. of Clinical Immuno.) and Ekins et al., (Analytica Chimica Acta.);

d) The rejection of claim 11 under 35 U.S.C. 103(a) as being unpatentable over Ekins et al., (EP 304,202), in view of either Ekins et al., (J. of Clinical Immuno.) or Ekins et al., (Analytica Chimica Acta.) in further view of Waggoner et al., US Patent (5,368,486);

e) The rejection of claim 12 under 35 U.S.C. 103(a) as being unpatentable over Ekins et al., (EP 304,202) in view of either Ekins et al., (J. of Clinical Immuno.) or Ekins et al., (Analytica Chimica Acta.) in view of Waggoner et al., US Patent (5,368,486) in further view of Lee et al., (US Patent 5,453,505); and

f) The rejection of claim 20 under 35 U.S.C. 103(a) as being unpatentable over Ekins et al., (EP 304,202) in view of either Ekins et al., (J. of Clinical Immuno.) or Ekins et al., (Analytica Chimica Acta.) in view of Northrup et al (US Patent 5,639,423).

It is noted however that the prior art rejections may be reinstated to overcome applicants' claims once the new matter has been removed.

Response to Arguments

3. Applicant's arguments with respect to claims 1-28 have been considered but are moot in view of the new ground(s) of rejection.

New Grounds For Rejection

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 1-36 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are drawn to a binding assay for sensing analyte mass in a liquid sample comprising a immobilization step; wherein the immobilized substrate comprises a plurality of microscopic sorbent zones wherein a zone comprises a multi-layer matrix of an analyte binding partner; a contact step; a tagging step; an illumination step; and detection step which thereby determines the analyte mass harvested from the defined volumes of sample

The written description in this case only sets forth that the sorbent zone has irregular topology, which has one irregular layer and not multiple layers of matrix or

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multiple layers of binding partner, therefore the written description is not commensurate in scope with the claims drawn to a multi-layer matrix of an analyte binding partner. Neither the specification nor the claims teach how to define a multi-layer matrix of an analyte binding partner. Neither the claims nor the specification teach how to obtain such multi-layer matrices. There is no guidance as to what the multi-layer matrices of an analyte binding partner are; or what binding partners can or cannot be used in the complex being claimed. The specification does not include structural examples of a multi-layer matrix of an analyte binding partner. Thus, the resulting multi-layer matrix of an analyte binding partner could result in a complex not taught and enabled by the specification.

Vas-Cath Inc. V. Mahurkar, 19 USPQ2d 1111, clearly states that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of *the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed*." (See page 1117). The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See *Vas-Cath* at page 1116).

Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 USC 112 is severable from its enablement provision (see page 115).

A skilled artisan cannot envision the detailed structure of a multi-layer matrix of an analyte binding partner, thus conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. An adequate description requires more than a mere statement that it is part of the invention and a reference to a potential method of isolating it. Furthermore, *In The Reagents of the University of California v. Eli Lilly* (43 USPQ2d 1398-1412), the court held that a generic statement which defines a genus of by only their functional activity does not

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provide an adequate description of the genus. The court indicated that while Applicants are not required to disclose every species encompassed by a genus, the description of a genus is achieved by the recitation of a representative number of molecules falling within the scope of the claimed genus. Therefore the full breadth of the claims meets the written description provision of 35 USC 112, first paragraph.

5. Claims 1-36 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a binding assay for detecting an analyte in a liquid sample comprising covalently immobilization achieved by derivatization of a deglycosylated commercial avidin preparation with a commercial photolabile linker moiety using 50mM phosphate buffered saline at pH 7.4 wherein the immobilized substrate comprises a plurality of microscopic sorbent zones wherein a zone comprises irregular topology; a contact step; a tagging step; an illumination step; and detecting fluorescent emission, does not reasonably provide enablement for a binding assay for sensing analyte mass in a liquid sample comprising a immobilization step; wherein the immobilized substrate comprises a plurality of microscopic sorbent zones wherein a zone comprises a multi-layer matrix of an analyte binding partner; a contact step; a tagging step; an illumination step; and detection step which thereby determines the analyte mass harvested from the defined volumes of sample. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

The specification teaches covalently immobilization achieved by derivatization of a deglycosylated commercial avidin preparation with a commercial photolabile linker moiety using 50mM phosphate buffered saline at pH 7.4 wherein the immobilized substrate comprises a plurality of microscopic sorbent zones wherein a zone comprises irregular topology at page 17 lines 25-33. Furthermore, example I in the specification teaches a biotin/avidin binding system using covalently printed array spots which have irregular topology at page 19 lines 16-20. Moreover, Example II and II require the use of the biotin/avidin system previously described to achieve "multi-layer" microscopic zones containing 10^5 to about 10^{10} molecules of analyte.

There is no teaching within the specification microscopic sorbent zones having the recited multi-layer property or the ability to contain 10^5 to about 10^{10} molecules of analyte without the biotin/avidin covalent binding system. The specification fails to teach examples of any multi-layer matrix of an analyte binding partner that meet the limitations of the claims. The specification lacks a description of what the multiple layers are or how to achieve the multiple layers of an analyte binding partner. The specification does not teach how detection of fluorescence emission thereby determines analyte mass harvested. Therefore, the specification fails to enable a binding assay for sensing analyte mass in a liquid sample comprising a immobilization step; wherein the immobilized substrate comprises a plurality of microscopic sorbent zones wherein a zone comprises a multi-layer matrix of an analyte binding partner; a contact step; a tagging step; an illumination step; and detection step which thereby determines the analyte mass harvested from the defined volumes of sample.

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Applicants' have provided no guidance to enable one of ordinary skill in the art as to how determine, without undue experimentation, a binding assay for sensing analyte mass in a liquid sample comprising a generic immobilization step wherein the zones comprises a multi-layer matrix of an analyte binding partner and detection step which thereby determines the analyte mass harvested from the defined volumes of sample; without teaching a multi-layer matrix or how to determine analyte mass merely from detecting fluorescence emissions.

Given the lack of guidance contained in the specification and the unpredictability for the ability to create a multi-layer matrix of an analyte or the ability to determine analyte mass based solely upon fluorescence emissions, one of skill in the art could not make or use the broadly claimed invention without undue experimentation. The specification fails to provide an enabling disclosure for a binding assay for sensing analyte mass in a liquid sample which could meet the limitations recited in the claims. There is no requirement or limitation for covalent immobilization to achieve the claimed matrix layer required to achieve the claimed limitations. In view of the lack of guidance contained in the specification and the unpredictability, one skilled in the art could not make or use the broadly claimed invention without undue experimentation.

6. Claims 1-36 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the

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application was filed, had possession of the claimed invention. This is a new matter rejection.

Claims 1-36 are drawn to a binding assay for sensing analyte mass in a liquid sample comprising a immobilization step; wherein the immobilized substrate comprises a plurality of microscopic sorbent zones wherein a zone comprises a multi-layer matrix of an analyte binding partner; a contact step; a tagging step; an illumination step; and detection step which thereby determines the analyte mass harvested from the defined volumes of sample.

There is no teaching of a multi-layer matrix of an analyte binding partner. The claims recite multi-layer matrix of an analyte binding partner, however there is no support in the specification for a multi-layer matrix of an analyte binding partner. The specification at page 19 recites that array spots have an irregular topology extending upwards vertically from the surface of the film. Therefore, the specification teaches one layer of binding partner immobilized to the surface, not multiple layers. Applicant pointed to page lines 16-33 for support, and asserts that general knowledge of the molecular structure entitles applicant to the claimed language. However, multi-layer is not equivalent to irregular topology. Irregular topology refers to one layer; therefore, the specification fails to provide support for the claims. Applicant has not pointed to support in the specification by page and line number. Thus, the amendment introduces new matter.

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7. Claims 1-36 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The term "multi-layer" in the claims is a relative term which renders the claim indefinite. The term "multi-layer" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. It is unclear how to define the term. It is unclear whether there are multiple layers of binding partner wherein avidin is on top of more avidin or if the immobilization created multiple layers from the surface of the film where the avidin can bind to the multiple layers. The metes and bounds of the term cannot be ascertained by the information provided by the specification. Clarification is required to overcome the rejection.

Conclusion

8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the

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shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ja-Na Hines whose telephone number is (703) 305-0487. The examiner can normally be reached on Monday through Thursday from 6:30am to 4:00pm. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith, can be reached on (703) 308-3909. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Ja-Na Hines
January 15, 2003


LYNETTE R. F. SMITH
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